

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/092,297	06/05/1998		PATRICIA A. BILLING-MEDEL	6107.US.P1-0	5922	
23492	7590	06/03/2003		•		
STEVEN F		- <del>-</del>	EXAMINER			
ABBOTT LA			TURNER, SHARON L			
DEPT. 377/A	AP6A			ART UNIT	PAPER NUMBER	
ABBOTT PA	ARK, IL	60064-6008	ARTONI	TAI ER NOMBER		
				1647	$\bigcirc$	
			·	DATE MAILED: 06/03/2003	$\mathcal{M}$	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No	). <b>(</b>	Applicant(s)								
		09/092,297	_	BILLING-MEDEL ET AL.								
•	Office Action Summary	Examiner		Art Unit								
	•	Sharon L. Turn	er	1647								
	The MAILING DATE of this communication appears on the cov r sheet with the correspondenc address											
Period for Reply												
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).												
Status	Becausive to communication(s) filed on 02 F	Sobruoni 2002										
1)⊠	Responsive to communication(s) filed on <u>03 F</u> This action is <b>FINAL</b> . 2b)  Thi		final									
2a) ☐	,—	s action is non-		acception on to th	a marita ia							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.												
Disposit	ion of Claims											
4)⊠ Claim(s) <u>10-16,25,30,33-35,38,39 and 45-55</u> is/are pending in the application.												
4a) Of the above claim(s) <u>34</u> is/are withdrawn from consideration.												
5)	Claim(s) is/are allowed.											
6)⊠	6)⊠ Claim(s) <u>10-16,25,30,33,35,38,39 and 45-55</u> is/are rejected.											
7)⊠	Claim(s) <u>10-16,25,30,33,35,38,39 and 45-55</u> is.	_										
8) 🖂		re subject to res	striction and/or ele	ction requiremen	t.							
Application Papers												
9) The specification is objected to by the Examiner.												
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.												
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.												
If approved, corrected drawings are required in reply to this Office action.												
12) The oath or declaration is objected to by the Examiner.												
Priority under 35 U.S.C. §§ 119 and 120												
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).												
a) ☐ All b) ☐ Some * c) ☐ None of:												
ŕ	1.☐ Certified copies of the priority documents have been received.											
	2. Certified copies of the priority documents have been received in Application No											
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).												
* See the attached detailed Office action for a list of the certified copies not received.												
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).												
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>												
Attachment(s)												
2) Notic	ee of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1.4</u>	4) <u> </u> 5) <u> </u> <u>5</u> . 6) <u> </u>	•	(PTO-413) Paper No atent Application (PT								

Application/Control Number: 09/092,297 Page 2

Art Unit: 1647

# **Continued Prosecution Application**

1. The request filed on 8-2-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/092,297 is acceptable and a CPA has been established. An action on the CPA follows.

- 2. The Examiner corrects Applicant in their statement of the pending claims. Currently claims 10-16, 25, 30, 33-35, 38-39 and 45-55 are pending.
- 3. The previous PTO-948 is noted with respect to the drawings.
- 4. Applicant's copy of the IDS submission of 6-17-1998 was apparently omitted from previous communication. It is appended herein.

#### **Election/Restriction**

5. Applicant's election of Group II, claims 10-16, 25, 30, 33, 35, 38-39 and 45-55 to the extent of SEQ iD NO's 5 and 17 in Paper No. 24 is acknowledged. It is noted that claims 45-55 are drawn to polynucleotides and thus are included in Group II. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 34 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 24.

# **Claim Objections**

6. Claims 10-16, 25, 30, 33, 35, 38-39 and 45-55 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in In re Weber \*\*,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

In instant case the claims are drawn to multiple sequences which lack unity as they fail to share common structure as evidenced by their multiple sequence identifiers.

- 7. Claims 10-16, 25, 30, 33, 35, 38-39 and 45-55 are objected to because of the following informalities: The sequences are required to be referenced via the terminology "SEQ ID NO:" as required by the sequence rules. Appropriate correction is required.
- 8. Applicant is advised that should claim 11 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims are deemed duplicates as the isolated polynucleotide is the same as the claimed composition of matter. If applicant's intention is to claim a composition such should be specified by the claim, i.e., by "A composition comprising...":

Application/Control Number: 09/092,297 Page 4

Art Unit: 1647

9. Claims 45-55 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 45-55 depend from claims 10, 11 and 38. The claims recite segments that are at least about 10, 15 and 20 contiguous amino acids or 10, 12, 15 or 20 nucleotides. The segment recitations broaden the scope of the base claim as less residues (less than full length sequences) are encompassed within the dependent claim but such shorter sequences are not encompassed by the independent claim. Correction is required.

### Specification

10. The disclosure is objected to because of the following informalities: The sequences are required to be referenced via the terminology "SEQ ID NO:" as required by the sequence rules. Appropriate correction is required.

#### **Sequence Compliance**

11. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

In particular, the specification and claims should be amended to reference all sequences by "SEQ ID NO:"

# **Priority**

12. The priority date awarded claims 10-16, 25, 30, 33, 35, 38 and 39 is the filing date of the present application, 6/5/98 based on a lack of written description of full length sequences, for instant SEQ ID NO:5 and SEQ ID NO:17.

Applicants have argued that support is provided for at least nucleotides 1-329 of the consensus sequence, and refers the Examiner to SEQ ID NO:3 and Figure 2 of priority application SN 08/869,579. In particular Applicants argue that the nucleotide positions referred to by the Examiner are actually "N" and thus that the residues may be any of A, C, G, T or U based on IUPAC-IUB codes. Applicants further argue that the remaining residues of the sequence should be given a date of 6-8-97 based on its submission to the ATCC.

These arguments have been fully considered but are not persuasive for the following reasons. As previously noted, a search of the parent application reveals that the consensus sequence in the parent is SEQ ID NO:3. Nucleotide sequence 819141 in the parent is SEQ ID NO:2. In comparison to instant SEQ ID NO:5, parent SEQ ID NO:3 possesses a nucleotide change at position 313 and parent SEQ ID NO:2 possesses two nucleotide changes at residues 12 and 247 (corresponding to nucleotides 78 and 313 of instant SEQ ID NO:5). Thus, the parent application fails to provide written description support for residues 66-329 of instant SEQ ID NO:5 as is instantly claimed by reference to sequence 819141. Disclosure of a "n" within the parent sequence fails to provide to the artisan any of the specific residues now recited. Also there is no basis for the incorporation of the IUPAC-IUB definition to the residues within the sequence listing. A review of the parent file reveals no indication in either the sequence listing or Figure for the "N" to represent any or all of the IUPAC-IUB codes. Applicants cannot evidence such meaning as supported by the priority document. In

addition the Examiner cannot award priority to a part of a sequence (a partial sequence) based upon changes from the original full length sequence disclosed in the priority document. The full sequence differs and therefore cannot benefit from priority. The priority date awarded instant claims is the instant filing date 6-5-98.

# Claim Rejections - 35 USC § 112

- 13. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 14. Claims 10-16, 25, 30, 33, 35, 38-39 and 45-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for BL172 sequences of SEQ ID NO's:1-5 and SEQ ID NO:17-20 that detect polynucleotide and polypeptide expression respectively within bladder tumors, does not reasonably provide enablement for the scope of the claims drawn to 90% or 50% identical sequences as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000. For example, Jobling et al, Mol. Microbiol., 1991, 5(7):1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of conserved structural components to both biological function and immunological recognition. The skilled artisan also recognizes that immunological responses depend upon the structural characteristics (conformation) of the particular protein (amino acid sequence) targeted.

Similarly, the artisan recognizes the variability in detecting various nucleic acid sequences using hybridization technology. In particular, sequences that differ at various residues may or may not hybridize and bind under various hybridization conditions, see in particular Sambrook et al., Ed., Molecular Cloning, Cold Spring Harbor Lab. Press, 1989, pp. 9.47-9.51 and 11.47-11.48.

Instant specification discloses particular BL172 sequences and a consensus sequence denoted as SEQ ID NO:5. Such sequences are exemplified in Figure 3A and 3B as being detected via RT-PCR analysis in bladder tumor samples. The specification also discloses a peptide of SEQ ID NO:18 that is detected using immune specific sera within bladder tumor samples as depicted in Figure 5. The specification contemplates the use of the related nucleic and amino acid sequences of SEQ ID NO's:1-5 and 17-20

in the detection of bladder tumors. While the specification has shown the utility of such sequences as it relates to bladder tumor, the specification does not teach the same utility for such widely divergent sequences that merely share 50% or 90% homology. However, the claims are drawn to such nucleic acid and peptide sequences which differ substantially in structure and presumably in function from the disclosed BL172 sequences.

The specification does not enable the broad scope of the claims which encompass a multitude of analogs or equivalents because the specification does not teach which residues can or should be modified such that the polynucleotides or polypeptides retain sufficient structural similarity to retain utility in hybridization/detection or the ability to evoke/recognize BL172 specific immune responses within bladder tumor tissue. The specification provides essentially no guidance as to which of the possible choices is likely to be successful and the skilled artisan would not expect functional conservation among such variable sequences. Thus, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the claims. The artisan recognizes that such structure is critical to bladder tumor specific detection. Moreover, the artisan recognizes the need for such markers to be specific in detection, see in particular Mc Neil et al., J. of the National Cancer Institute 88(23):1704-5, 1996 (IDS), Abbate et al., Anticancer Res., 18(5B)3803-5, 1998 and Jacobs et al., Current Problems in Cancer, 15(6):299-360, 1991 (IDS). The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

Art Unit: 1647

Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

Thus, for the aforementioned reasons, the artisan cannot make and use the claimed invention without further undue experimentation.

Claims 10-16, 25, 30, 33, 35, 38-39 and 45-55 are also rejected under 35 U.S.C. 15. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a BL172 sequences consisting of SEQ ID NO's1-4, a consensus sequence indicated as SEQ ID NO:5 and an open reading frame peptide represented as SEQ ID NO:17 including various fragments thereof indicated as Seq ID NO's 18-20, which are disclosed as having the utility of being expressed within/detecting bladder tumor. However, the claims as written include polynucleotides comprising various fragments and homologues, and sequences that encode various polypeptides that vary substantially in length and also in amino acid composition. The instant disclosure of nucleic acids of SEQ ID NO's: 1-5 encoding a single polypeptide, that of SEQ ID NO:17 with the instantly disclosed specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of

Art Unit: 1647

species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide sequence SEQ ID NO: 17 and various sequences encoding it that are proposed to possess the same activity in detection (SEQ

ID NO's:1-5). However, the artisan recognizes the unpredictability in the art with respect to detection based upon divergent sequences under various hybridization conditions, see in particular Sambrook et al., as set forth above. Further the artisan recognizes the unpredictability in the art based upon divergent amino acid structure and immune recognition, see in particular Skolnick et al., and Jobling et al., as set forth above. While the specification apparently asserts that 50% or 90% variants would be suitable for description of the genus of polynucleic acids now encompassed, there is no correlation or nexus provided between possession of such variable structural features and the ability to detect bladder tumors. Thus, it is not clearly conveyed that possession of any polynucleotide or polypeptide having such structural features in common would possess the functional feature of bladder tumor detection. Without such detection, the structural features alone are an inadequately description of the genus of polynucleotide for which utility is provided in the detection of bladder tumor.

For these reasons adequate written description is not provided to the claims.

- 16. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 17. Claims 25, 30 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 18. Claims 25 and 38 recite particular elements via a Markush but fail to delimit the last element via "and X". Clarification is required.

Application/Control Number: 09/092,297 Page 12

Art Unit: 1647

19. Claims 30 recites "a nucleic acid sequence encoding at least one eptiope" wherein the sequence is "a complement thereof". Yet, the artisan recognizes that the complementary sequence is of the non-coding strand and is unrelated to production of the amino acids of SEQ ID NO's: 17-20. Removal of this element of the Markush is required. Further, the recitation is followed by the phrase "encodes a polypeptide wherein...". The clause is not linked such that the artisan can recognize the further elements or limitations intended. Clarification is required.

#### Claim Rejections - 35 USC § 102 or 103

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

- 22. Claims 10-16, 33, 35, 39, and 48-55 are rejected under 35 U.S.C. 102(b) as being anticipated by and also on sale and publicly used from Boehringer Mannheim Biochemical, 1991 catalog, page 557. The claims are drawn to test kits and isolated polynucleotides that are complements. Boehringer teaches and sells random hexamer primers that are complements to all nucleic acid sequences and which is available in a container.
- 23. Claims 10-16, 35, 38, 45, 46, and 48-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al, EST Databse Accession No. AA195677 alignment, 19 May, 1997.

Claims 10-16, 25, 30, 35, 38 and 45-55 are drawn to polynucleotide sequences which bind to or encode contiguous amino acids of SEQ ID Nos:1-5, sequence 819141, and SEQ ID Nos:17-20. Hillier et al teach nucleotides which bind to or encode contiguous amino acids selected from the group consisting of SEQ ID Nos:1-5, sequence 819141, and SEQ ID NO:17-20, see alignment with SEQ ID NO:17, amino

Art Unit: 1647

acids 102-117, backtranslation to nucleic acids 460-413. Thus, the reference teachings anticipate the claimed invention.

Applicants argue that they are entitled to their priority date and that the 1.131 declaration supercedes the reference.

Applicants response has been fully considered but is not persuasive because as set forth above there is no basis for priority to the sequences now claimed and further a 102(b) may not be obviated by a declaration. Thus, the rejection is maintained for the reasons of record.

24. Claims 10-16, 25, 30, 35, 38, and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al, EST Databse Accession No. AA195677 alignment, 19 May, 1997 in view of Expression of Cloned Genes in E. coli, Sambrook et al, Cold Spring Harbor Laboratory, 1989.

Claims 10-16, 25, 30, 35, 38 and 45-55 are drawn to polynucleotides which bind and encode contiguous amino acids, expression vectors and host cells containing such polynucleotides of SEQ ID NO's:1-5, 17-20 and sequence 819141. Hillier et al, disclose polynucleotides with 100% nucleic acid identity, to nucleotides encoding amino acids from cDNA clones, see attached alignments.

However Hillier et al does not expressly teach a transfected host cell and a method of producing the polypeptide fragments using the host cell transfected with the polynucleotide fragments.

Sambrook et al teach the expression of polypeptide fragments from cloned DNA sequences, using the DNA sequence, a vector and host cells transformed with the vector. Given the teachings of Sambrook et al it would have been prima facie obvious

for one of skill in the art knowing the DNA sequence of Hillier and the techniques of Sambrook to insert the DNA sequence into an expression vector, transfect host cells and produce the polynucleotides and polypeptides as claimed. One of skill in the art would have been motivated to do so based on the ease and effectiveness taught by Sambrook et al for obtaining abundantly produced polypeptides for use in further analysis of the particular proteins properties and functional characteristics and would have expected success given the high skill in the art.

Applicants argue that they are entitled to their priority date and that the 1.131 declaration supercedes the reference.

Applicants response has been fully considered but is not persuasive because as set forth above there is no basis for priority to the sequences now claimed and further a 102(b) may not be obviated by a declaration. Thus, the rejection is maintained for the reasons of record.

#### Status of Claims

25. No claims are allowed.

#### Conclusion

26. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is

Art Unit: 1647

(703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D. May 30, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600